



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,538	04/20/2004	John C. Pulford	A0420/7017P1	3890

21127 7590 08/10/2005

KUDIRKA & JOBSE, LLP
ONE STATE STREET
SUITE 800
BOSTON, MA 02109

EXAMINER

COMSTOCK, DAVID C

ART UNIT PAPER NUMBER

3732

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/828,538

Applicant(s)

PULFORD ET AL.

Examiner

David Comstock

Art Unit

3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☒ Claim(s) 30-42 is/are allowed.
6) ☒ Claim(s) 1-29 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 20 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Objections to Amendment - 35 U.S.C. 132

The amendment filed 20 May 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: In claim 1 and claim 19, "non-dilatable" lacks support in the original disclosure.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 and 19-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new language in claims 1 and 19, "non-dilatable", does not have support in the originally filed disclosure.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-11, 13, 14, 19, 20, 22-27 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Yuen (4,984,564).

Yuen discloses a surgical retractor device 10 comprising an inner ring 14, an outer ring 12, and an elongate sleeve 16 connected to and extending between the inner and outer rings (see Fig. 2; col. 2, lines 6-55; and col. 3, lines 4-21). The rings comprise fluid tight channels, with respect to the exterior of the device. The device includes a radial support structure 30 (see Figs. 3-5). Since the rings and sleeve are all connected to each other, the channels of the inner ring and outer ring can be considered part of the elongate sleeve. Nevertheless, since the rings comprise a discrete identifiable structure, namely rings, the channels defined within and by the rings can be considered discrete fluid tubes. Dilation of the rings results in an increase in the diameter of the device (cf. Figs. 1 and 2 or 4 and 5). The fluids used may be pressurized liquid or gas (see col. 4, lines 38-40 and 57-59). The device includes a check valve--i.e. a valve that restrains or inhibits a fluid, namely, the valves 18, 22, 26, 28 having caps--in a fluid pathway between the pressurized source and the rings (see Figs. 1-5 and col. 3, line 66 - col. 4, line 4). The device also includes an output fluid pathway 22 (e.g., Fig. 1 and col. 3, lines 10-27). A method of using the device is disclosed (see col. 4, lines 34-66).

The device is inserted in an incision an undilated state whereupon it is inflated with pressurized air or fluid. After the surgical procedure has been completed, the fluid is vented from the rings through the output pathway in order to remove the device from the incision.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3 and 21, as best understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over Yuen (4,984,564) in view of Brinkerhoff et al. (5,366,478; cited by Applicant).

Yuen discloses the claimed invention except for the springs. Brinkerhoff et al. disclose a similar device comprising flexible stiffening rings, i.e. springs, 19, in order to provide shape when the device is deflated and facilitate insertion into a body cavity (see Fig. 1 and col. 4, lines 28-36). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the retractor device of Yuen with springs, in view of Brinkerhoff et al., in order to provide shape when the device is deflated and facilitate insertion into a body cavity. With regard to the ring having separate ends in Yuen, it still would have been obvious to provide the device of Yuen with the springs, as set forth above, since it has been held that constructing a formerly integral structure (i.e. the continuous ring springs of Brinkerhoff et al) in various

Art Unit: 3732

elements (i.e. the ring having separate ends) involves only routine skill in the art.

Nerwin v. Erlichman, 168 USPQ 177, 179.

Claims 12 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yuen (4,984,564) in view of Kleaveland (3,863,639).

Yuen discloses the claimed invention except for explicitly disclosing that the pressure source can be a syringe. Kleaveland discloses a similar device that is pressurized with any of various different functionally equivalent pressurizing devices known in the art, e.g. a syringe (see Fig. 1 and col. 3, lines 45-60). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute a syringe for any of numerous pressurizing means known in the art, in view of Kleaveland, as these were functionally equivalent pressurizing means known in the art at the time of the invention, and as such, would have merely required routine skill to implement.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Art Unit: 3732

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,723,044 ('044). Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences involve only obvious modifications to the subject matter of claim 1 of '044.

Claim 1 of '044 discloses the inner and outer rings and the elongate sleeve, as well as the pre-loaded rotational torque. Claim 1 does not disclose the rings having a minimum diameter of 20 cm. With regard to claims 15 and 16, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the rings with a diameter of 20 cm or with any of numerous other dimensions, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. With regard to claims 17 and 18, it also would have been obvious to form the rings of an elastic material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Allowable Subject Matter

Claims 30-42 are allowable over the prior art of record.

Response to Arguments

Applicant's arguments filed 20 May 2005 have been fully considered but they are not persuasive.

Applicant's arguments depend on subject matter not supported in the original disclosure, as set forth above.

With regard to Brinkerhoff, the rings necessarily exert an outward radial force when acted upon by an inward radial force. Thus, they are capable of meeting the claim limitations. It is noted that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

In response to applicant's argument that Kleaveland is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the device of Kleaveland is in applicants field of endeavor, namely, surgical devices. In addition, the device of Kleaveland is reasonably pertinent to the problem of inflating a surgical device.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

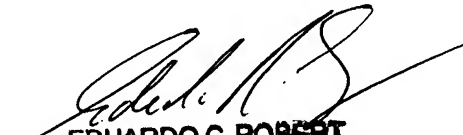
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. Comstock
7 August 2005


EDUARDO C. ROBERT
PRIMARY EXAMINER